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Required Report - public distribution

Date: 7/14/2010

GAIN Report Number: EC1005

Ecuador

Biotechnology - GE Plants and Animals

2010 Ecuador Biotechnology Report: Policy, Trade, Marketing of Genetically Engineered Crops

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Report Highlights:

Ecuador maintains a number of anti-biotech laws and regulations, but there is no enforcement and trade in corn and soybean products continues. However, this situation can change quickly. Ecuador's National Assembly has not yet decided whether to draft and approve a Law of Seeds, among other laws and regulations that could restrict trade. Efforts are needed to strengthen the institutional capacities to establish and enforce regulations based on science and international standards. On the other hand, in recent years, Ecuadorian public and private research institutions have increased their activities related to agri-biotechnology.

Section I. Executive Summary:

Ecuador has a number of laws and regulations that could impact the importation, distribution and use of products derived from biotechnology, but it lacks a specific law that directly regulates biotechnology. Article 401 of the 2008 Constitution declares Ecuador free of transgenic crops and seeds. However, the same article grants the President the exclusive authority to allow imports of agricultural crops and seeds that may have been produced using genetic modification. In February 2009, Ecuador's legislative body approved a Food Sovereignty Law aimed at regulating the use of biotechnology. The law was published in the National Register on May 5, 2009. This law is very vague and does not provide any specifics on the use of biotechnology in agriculture. It is expected that Ecuador's National Assembly will consider at least one additional law or ruling regarding seeds and agricultural research. In the interim, imports have continued normally.

In April 2006, Ecuador enacted the Food and Nutrition Security law that invokes the precautionary principle and calls for prohibitions on the use, handling, trade or importation of any food products that are, or contain, genetically engineered organisms (GEOs). The regulation initially created trade problems with soybean meal and soybean oil imports, but backlash from the industries that use these products as inputs has led the government to drop any enforcement measures. As Ecuador imports about 29 percent of its corn demand, 89 percent of cotton, and 90 percent of soybean meal and oil, these products have been entering with no restrictions or review.

Ecuador ratified the Cartagena Protocol on Biosafety in November 2002, and its general policies on biosafety are expressed in several existing laws, including the Constitution.

In the last few years, Ecuador's public research institutions, due to increased levels of government funding, and private university and research centers, have notably increased their human and infrastructure capabilities making Ecuador a country with a high potential to develop its biotechnology sector.

Section II. Plant Biotechnology Trade and Production:

Traditionally, the Ecuadorian Institute for Agricultural Research (INIAP), the main venue for agri-biotechnology research, had claimed that given the incipient technology and infrastructure available Ecuador does not have the capacity to conduct any GEO-related research. INIAP's research has focused on improving the quality of seeds through hybrids for cocoa, potatoes, tomato, corn, rice and soybeans. However, a 2008 Inter-American Institute for Cooperation in Agriculture assessment of agri-biotechnology in Latin America suggests that Ecuadorian laboratories have the capability to produce transgenic plants.

Furthermore, a 2009 INIAP assessment of its own capacities as well as other biotechnology laboratories across Ecuador suggests that public and private interest in biotechnology research has increased tremendously in the last few years. According to INIAP, the first biotechnology laboratory in Ecuador opened in 1978. From then until 1998 the number of biotechnology labs has increased to 11. As of March 2009, there were 53 laboratories, according to INIAP. The increase responds to demand conditions for tissue culture and somatic embryogenesis, molecular biology applications and diagnosis. Agricultural sectors that seem to be using biotechnology to a larger extent include the flower sector, the banana and cacao sectors, as well as the aquaculture industry. Seventy one percent of the labs report to be performing research on plants or agriculture, while 16 percent on microorganisms, 12 percent on livestock and aquaculture and 1 percent provide training and education services. INIAP has also reported that there are six additional laboratories dedicated as germplasm conservation facilities. In 2008, Ecuador had 32 professionals with a PhD level

education, 45 with a Master's degree or equivalent and 96 college graduates in the area of biotechnology. Currently, even though Ecuadorian labs have the infrastructure to work on genetically engineered (transformed) organisms, there has been only one attempt to accomplish that in disease resistance of banana plants at a local university biotechnology facility. Ongoing research there includes development of cisgenic banana plants.

Biotechnology techniques have been used traditionally in the following crops: bananas, sugarcane, palm oil, cacao, ornamental plants and coffee; either for improvement or diagnosis generally, as well as in the study of biological agents to control pests and diseases. Work on shrimp have also been extensive.

Areas of future research interest among Ecuadorian biotechnology laboratories and professionals include efficiency in the production of in-vitro plants, in-vitro conservation, molecular markers, Cryopreservation, diagnosis methods, assisted plant breeding, genetic transformation, genomics, bioinformatics, biosafety, among others.

Given the nonexistence of a framework to regulate biotechnology, Ecuador does not allow the importation of seeds containing GEOs. According to the Ministry of Agriculture, all seeds used for corn, soybean and other crops are either hybrids developed by the INIAP or other certified imported seeds that do not contain GEOs, and which must have passed through a rigorous in-country certification process. Existing law, however, does not properly specify or authorize any government agency to conduct such certification process due to a typo in the text of the law appearing in the National Register.

A growing proportion of the supply of corn, cotton, soybean meal and soybean oil for industrial use is of foreign origin. A brief description of the commercial situation of these products follows:

- Presently, Ecuador imports 29 percent of its corn demand. Imports reached 352,000 MT in 2009, 84 percent of which originated in the United States, with the remainder coming from Brazil and Argentina.
- Ecuador purchased 89 percent (16,419 MT) of its cotton needs (18,383 MT) from foreign sources in 2009, of which 66 percent (10,852 MT) came from the United States.
- Soybean meal and oil imports are also rising, with Argentina as the traditional main supplier. However, depending on prices, Ecuador purchases significant volumes of soybean meal from the United States. Overall, imports of soybeans, soybean meal and soybean oil reached 656,000 MT in 2009, 75 percent of which came from the United States, 11 percent from Argentina and 10 percent from China.

Another concern arises when Ecuador currently sources high percentages from its corn, cotton and soybean requirements to fulfill its meal needs from foreign buyers— mainly the United States, Brazil and Argentina – without any specific biotechnology requirements. The animal feed as well as the poultry, pork, cooking oil, tilapia, shrimp, tuna canning, feed manufacturing and snacks industries currently use these products in their formulations, and it is unlikely that Ecuador would have the capacity to supply this demand in the near future. Therefore, the issuance of additional restrictive rules would not only hurt U.S. export interests, but would also complicate the survival of large local industries further jeopardizing Ecuador's efforts to achieve food security and combat malnutrition.

Section III. Plant Biotechnology Policy:

Ecuador seems to have developed in recent years the human and infrastructure resources to conduct high-level research on agricultural biotechnology, although it still relies on scientific protocols developed

elsewhere. In the biosafety debate over genetically engineered crops, Ecuador has remained incapable of submitting enough scientific evidence about the possible risks of the use of biotechnology as a way to justify restrictive trade measures against biotech foods. However, it is clear that Ecuadorian authorities are worried about the issue of “dependence” from foreign technologies and imports of certain products, such as planting seeds and oilseeds. There is also an increased fear from farmers that allowing biotech seeds will hurt their plantations, and that using these products will turn their production capacity into a dependency relationship with multinational corporations. Nevertheless, Post understands that producers are highly aware of the benefits of improved seeds brought illegally into the country from Argentina and Brazil that have been planted by several farmers.

Ecuador’s 2008 New Constitution and Regulatory Framework Background

According to the Environmental Management Law, the Ministry of Environment of Ecuador is the entity in charge of regulating the production, propagation, research, use, trade and importation of GEOs. The same law establishes the Ministry of Environment’s coordination authority over the decentralized Environmental Management System and allows for other institutions, such as the Ministries of Agriculture, Health, and Foreign Trade to have direct authority over their own issues.

Although the institutions are in place, there is no specific law to regulate biotechnology and biosafety. The environmental management law is very broad and does not deal with specific issues of agricultural biotechnology and biosafety. However, a general national policy on biosafety is expressed in existing laws. Article 401 of the 2008 Constitution declares Ecuador free of transgenic crops and seeds. However, the same article grants the President the exclusive authority to allow imports of agricultural crops and seeds that may have been produced using genetic modification. In February 2009, Ecuador’s legislative body approved a Food Sovereignty Law aimed at regulating the use of biotechnology. This law is vague and does not provide any specifics on the use of biotechnology in agriculture. It is expected that Ecuador’s next National Assembly will consider at least one additional law or ruling regarding seeds and agricultural research. In the interim, imports have continued normally. Interested private sector industries continue to work with Ecuadorian authorities to develop implementing regulations that would not impede trade in products derived from biotechnology.

The second section of Article 401 contains implications that might affect the development of biotechnology in Ecuador. This section states that the State will regulate under strict norms of biosafety, the use and development of modern biotechnology and its products, as well as biotechnology experimentation, use, and commercialization. It further states that the application of risky or experimental biotechnology is forbidden. This last part has awakened a lot of controversy among Ecuador’s scientific community as it is not clear under what parameters risky or experimental will be defined. Overall, the scientific community is concerned that the scope of work of highly trained scientists could be significantly reduced.

Other national laws such as the Health Code, the Consumer Rights Protection Law, the Agricultural Development Law, the Law of Seeds, and the Plant and Animal Health Law are of general applicability but do not provide specific guidance on biosafety issues.

On the international front, as a signatory of the Convention on Biological Diversity and the Cartagena Protocol on Biosafety, Ecuador is obliged to issue policies and regulations in accordance with the precepts of these international agreements. Also, as a member of the Andean Community of Nations, Ecuador is subject to Andean Decision 523, which states an Andean Strategy on Biodiversity that must be taken into account by all members when issuing their regulations on biosafety.

Until April 2005, there was a proposed text for a “Law of Conservation and Sustainable Management of the

Biodiversity” (Biodiversity Law) that would have served as a framework for Ecuador’s regulations on biosafety and biotechnology. The text aimed to provide technical standards and a comprehensive regulatory system that would have ensured proper control of products derived from biotechnology and would not unjustifiably block trade. This proposed bill was first submitted to Congress in April of 2002 and later debated although a consensus was never reached. A second debate was scheduled for February of 2003, but it never happened. That time, political parties controlled by indigenous, environmentalists and leftist groups in the Ecuadorian congress used filibusters to delay a decision. Finally, the proposal was filed away and these groups counter-attacked by adding two articles to a controversial Food and Nutrition Security bill that banned any production, use, import or trade of biotech foods in Ecuador.

Currently no organization or government agency is either legally authorized or asked to perform analysis of food products entering the country to assess the presence of genetically engineered ingredients. Protocols for testing have not been either adopted or created locally.

Specific Laws dealing with Biosafety and Biotechnology

Labeling: The Law for Protection of Consumer’s Rights

This law, enacted on July 10, 2000, regulates the supplier-consumer relationship by promoting knowledge and protection of consumer’s rights. It has a clause by which ambiguous dispositions should be interpreted to favor the consumer. The public entity in charge of enforcing this law is the Office of the Ombudsman. However, little or nothing has been done to exercise such enforcement.

Regarding Biotechnology, article 13 and article 14 of this law state clearly that “in the case of products sold for human or animal consumption that had been produced using biotechnology or any type of genetic manipulation, labels must warn of this fact using highlighted characters” and provide labeling requirements for genetically engineered food products. This regulation is not being enforced. Indeed, there are no products in the Ecuadorian market, whether imported or locally produced, that contain labels declaring GEO content

This law leaves room for specific laws dealing to regulate specific health and safety issues. This is currently the only law in place that deals with biotechnology labeling.

An inter-institutional working group that includes Ecuador’s Standardization Institute and the Ministry of Health was formed to prepare new standards for food labeling. The proposed text is still waiting to be submitted to the WTO for comment, in part due to changes in Ecuador’s legislative body. Based on the provision of article 13 of the Consumer Rights law, this proposed standard would set a requirement for biotech foods to be labeled as to contain GEOs, and for foods containing GEO ingredients to declare the percentage of such GEOs in their composition.

Imports of Vegetable Materials and Animals: Laws of Animal and Vegetable Health

Article 4 of the Vegetable Health law establishes that any import of vegetable materials for propagation, including those used for research, must obtain an authorization from the Ministry of Agriculture. In the case of animals used for genetic improvement, the Animal Health law provides requirements and authorizations from the Ministry of Agriculture, and establishes the obligation to comply with Andean regulations.

Authorized Biotech Foods: Rules for Sanitary Registration and Control

This regulation deals with the sanitary registration of national and imported food and beverage products for human consumption in Ecuador. Article 50 of this regulation makes reference to fines and penalties, which will be applied according to the dispositions of the Consumers Rights Protection law.

Furthermore, article 54 mentions that biotech and/or GEO foods will only be authorized to enter Ecuador when such products comply with the requirements of the Ministry of Health, which would issue a positive list of transgenic products authorized for import. Such a list does not exist. It is not apparent when Ecuador's National Assembly will address the issue.

Food Sovereignty Law 2009

The main objective of this law is to promote and provide access for the population of Ecuador to food and nutrition and agricultural land. It declares food security as a primary national policy and creates the inter-ministerial "National System of Food Sovereignty and Nutrition" and the National Food Sovereignty Conference. The law is based on Constitutional principles that guarantee people's rights. This is not technical and limits its ruling to broad and vague principles.

Article 26 declares Ecuador free of GEOs. It continues to mention that the introduction of seeds and crops genetically engineered will only be possible in the case of national interest properly recognized by the Office of the Presidency. The state is given the authority to regulate under strict biosafety norms the use and development of modern biotechnology and its products, as well as experimentation, use, and commercialization. The use of risky or experimental application of biotechnology is forbidden, although no definition of risky or experimental is given.

Article 26 also mentions that raw materials that contain transgenic ingredients can be imported and processed only when they fulfill health and safety requirements, and that they are not capable to reproduce, while respecting the precautionary principle so that they do not threaten human health, food sovereignty and the ecosystems. It adds that products processed using transgenics must be labeled according to the law that regulates consumers' rights. This is the most controversial part of this law. While it requires importers to bring in only material that cannot be reproduced, it also requires for take food sovereignty and ecosystems to be taken into consideration. Additional laws and regulations on biodiversity, biotechnology, usage and commercialization of biotechnology products, animal health, plant health are mentioned as the set of norms that will establish the mechanisms of food safety and the instruments that will guarantee respect to the rights of Nature and the production of safe foods while establishing preferred treatment to micro-entrepreneurs, microenterprises or micro and small and medium size producers.

This is not the first time that a law like this issued. In May 2005, after the passage of a similar law, the Ministry of Agriculture stopped imports of soybean meal and soybean oil for three weeks. This caused great difficulties to the poultry, animal feed, cooking oil and tuna canning industries. Even though the provisions of this law were initially enforced, a technical error found in the text gave Ecuador's Attorney General enough reason to declare the bill unenforceable. Since then, trade has flowed normally and there have not been any reports of shipments being stopped or import permits being denied as a result of this regulation. Industry groups are expected to continue to exert pressure on the Government of Ecuador to ensure any additional norms address their concerns and that trade will not be disrupted.

The Health Code

As a continuation of push against biotechnology, Ecuador's Congress passed a new Health Code law in December 2006. This is a general law dealing with the protection of human health, and includes provision on matters of food safety. This bill literally reintroduced the provisions of the Food and Nutrition Security law and corrected its technical errors. However, it does not resolve the issue of Ecuador's lack of capacity to determine the safety of food products derived from biotechnology. The law also leaves the implementation of its biotechnology-related dispositions to the application rules that are still to be issued.

The Ministry of Health of Ecuador has the lead in writing draft rules for this law, which cannot be fully enforced without them. For this reason, imports of food products have continued normally, and the Ministry of Agriculture has not issued a position on the matter. These rules are not likely to be available anytime soon. Affected private sector industries plan to work with Ecuadorian authorities to develop implementing regulations that would not impede trade in products derived from biotechnology.

Section IV. Plant Biotechnology Marketing Issues:

The use of biotechnology in food is a new and intricate topic for discussion in Ecuador. The majority of consumers are not aware of the existence of food products derived from the use of biotechnology, and in a country with abundant patches of food insecure regions, this may not be an issue of major concern to the poor and struggling majority. However, environmental and indigenous groups are fully aware of the issue, and although they lack scientific evidence of the implications of biotechnology, they have been successful in keeping any biotech-related products either labeled or advertised as such from entering Ecuador, as a requirement to preserve this country's mega-biodiversity. In addition, continued application of the Precautionary Principle in Ecuador is likely to create further trade controversies.

There is no specific information related to the market acceptance of biotech foods. However, it is believed that if biotech products are required special labels "alerting" of presumable harmful characteristics, a considerable portion of Ecuadorian consumers will certainly reject them.

Section V. Plant Biotechnology Capacity Building and Outreach:

Even with the lack of accurate information about biotechnology among consumers and policymakers in Ecuador, several activities related to biotech capacity building and outreach have been carried out by government institutions and industry. The FAS Quito has also been active in the past few years on issues related to promoting biotechnology and agricultural research. In October 2008, the use of biotechnology in food is a new and intricate topic for discussion in Ecuador. The majority of consumers are not aware of the existence of food products derived from the use of biotechnology, and in a country with abundant patches of food insecure regions, this may not be an issue of major concern to the poor and struggling majority. However, environmental and indigenous groups are fully aware of the issue, and although they lack scientific evidence of the implications of biotechnology, they have been successful in keeping any biotech-related products either labeled or advertised as such from entering Ecuador, as a requirement to preserve this country's mega-biodiversity. In addition, continued application of the Precautionary Principle in Ecuador is likely to create further trade controversies.

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In October 2008, FAS Quito representatives attended a conference on agricultural biotechnology which intended to start the process to define a strategy to address biotechnology and environmental issues on agriculture. In August 2009, FAS Quito organized six outreach conferences on biotechnology. Attendees included government officials and academics, as well as university students. FAS Quito is also organizing a workshop for journalists on how to communicate to the public biotechnology-related topics. In the future, FAS Quito would like to send a select group of journalists to Argentina for a tour of major biotechnology facilities in that country with the expectation that the journalists will report on the advantages of biotechnology for food security purposes and sustainable agriculture. FAS Quito often participates in seminars on biotechnology in agriculture to college students and faculty.

FAS Quito has also made use of Cochran fellowships and scientific exchanges to educate policymakers,

scientists, and others through short training courses on biotechnology, food safety and biosafety issues.

Further efforts are being made to continue with this type of assistance by using USDA's food aid programs to improve Ecuador's trade capacity by providing funds for international agricultural training and in-country research.